Random Capillary Blood Glucose Cut Points for Diabetes and Pre-Diabetes Derived From Community-Based Opportunistic Screening in India

SURESH SOMANNAVAR, MD
ANBAZHAGAN GANESAN
MOHAN DEEPA, MSC, PHD
MANJULA DATTA, MD, DCH, MSC, FRCP
VISWANATHAN MOHAN, MD, FRCP, PHD, DSC

OBJECTIVE — To determine random capillary blood glucose (RCBG) cut points that discriminate diabetic and pre-diabetic subjects from normal individuals.

RESEARCH DESIGN AND METHODS — RCBG was performed in 1,333 individuals randomly chosen from 63,305 individuals who had participated in an opportunistic screening program. An oral glucose tolerance test was also performed by venous plasma glucose on an autoanalyzer. RCBG cut points that discriminate diabetes, impaired glucose tolerance (IGT), and impaired fasting glucose (IFG) were determined using receiver operating characteristic curves.

RESULTS — Using 2-h plasma glucose ≥200 mg/dl (11.1 mmol/l) criterion, the RCBG cut point of 140 mg/dl (7.7 mmol/l) gave the highest sensitivity and specificity. For 2-h plasma glucose ≥200 mg/dl (11.1 mmol/l) and fasting plasma glucose (FPG) ≥126 mg/dl (7.0 mmol/l) criteria, either 2-h plasma glucose ≥200 mg/dl (11.1 mmol/l) or FPG ≥126 mg/dl (7.0 mmol/l) criterion, and the FPG ≥126 mg/dl (7.0 mmol/l) criterion, RCBG cut point was 143 mg/dl (7.9 mmol/l). RCBG cut points for IGT, IFG according to World Health Organization criterion, and IFG according to American Diabetes Association criterion were 119 mg/dl (6.6 mmol/l), 118 mg/dl (6.6 mmol/l), and 113 mg/dl (6.3 mmol/l), respectively.

CONCLUSIONS — Asian Indians with RCBG >110 mg/dl at screening can be recommended to undergo definitive testing.

Diabetes Care 32:641–643, 2009

Approximately 50–70% of people with diabetes remain undiagnosed in both developed (1) and developing countries (2), and these individuals often present with diabetes complications (3). It is established that good control of diabetes can prevent complications. Undiagnosed diabetes and pre-diabetes therefore need to be detected and treated early through community-based screening (4).

Definitions of diabetes are usually based on fasting or postprandial glucose. However, random capillary blood glucose (RCBG) is the most convenient way to reach large numbers of people. A few studies in Western countries (5,6) have tried to correlate RCBG with 2-h plasma glucose or fasting plasma glucose (FPG) (the basis for the World Health Organization [WHO] and American Diabetes Association [ADA] definitions) but none from India, which has the largest number of people with diabetes globally (7). There are also no data on RCBG cut points for pre-diabetes states such as impaired fasting glucose (IFG) and impaired glucose tolerance (IGT). This is particularly relevant because IFG now has two definitions: ≥100 mg/dl (5.6 mmol/l) according to ADA (8) and ≥110 mg/dl (6.1 mmol/l) according to WHO (9).

The aim of this study, carried out in a community setting in southern India, was to derive RCBG cut points that discriminate diabetic from nondiabetic and pre-diabetic from non–pre-diabetic individuals.

RESEARCH DESIGN AND METHODS

— Between September 2004 and September 2007, 774 opportunistic diabetes screening camps evaluating 103,878 people were conducted in various parts of Chennai (formerly Madras), India, with a population of 5 million in southern India, as part of the Prevention Awareness Counselling and Evaluation (PACE) Diabetes Project. Of these, 76,645 (73.8%) individuals underwent an RCBG test using One Touch Ultra (Lifescan, Johnson & Johnson, Milpitas, CA). The detailed methodology of this project is described elsewhere (10).

Individuals with self-reported diabetes (n = 13,340) were excluded. Of the remaining 63,305 subjects, 1,500 individuals were randomly selected and invited to attend Dr. Mohan's Diabetes Specialities Centre, a tertiary referral center for diabetes care, to undergo an oral glucose tolerance test within the next 2 to 3 days. A total of 1,333 individuals responded to the invitation (88.9% response rate). A sample was drawn for FPG estimation, 75 g of oral glucose was given, and a second sample was drawn at 120 min (2-h plasma glucose).

Statistical analysis

Statistical analysis was performed using SPSS for PC Windows, version 10.0 (SPSS, Chicago, IL). Receiver operating characteristic curves were plotted using sensitivity and 1-specificity for different cutoff values of RCBG. Using the receiver operating characteristic technique, comparison of sensitivity with specificity was made over the entire range of RCBG cut

From the Madras Diabetes Research Foundation and Dr. Mohan's Diabetes Specialities Centre, World Health Organization Collaborating Centre for Noncommunicable Diseases Prevention and Control, Chennai, India.
Corresponding author: Viswanathan Mohan, drmohans@vsnl.net.
Received 26 February 2008 and accepted 28 November 2008.
Published ahead of print at http://care.diabetesjournals.org on 10 December 2008. DOI: 10.2337/dc08-0403.

Table 1—*RCBG cut points with respect to diabetes, IGT, and IFG in Asian Indians*

	n (%)	RCBG (mg/dl)	RCBG cut points	Sensitivity	Specificity	PPV	AUC	Overall accuracy (%)
Diabetes								
2-h PG ≥200 mg/dl or FPG ≥126 mg/dl	238 (17.9)	187.3 ± 67.0	143	78.6	83.9	51.5	0.872	82.9
2-h PG ≥200 mg/dl	185 (13.9)	198.6 ± 69.1	140	86.5	80.7	42.0	0.900	81.5
FPG ≥126 mg/dl	194 (14.6)	193.3 ± 70.2	143	80.4	81.7	42.9	0.873	81.5
2-h PG ≥200 mg/dl and FPG ≥126 mg/dl	141 (10.6)	210.5 ± 71.8	143	89.4	80.2	34.8	0.919	81.2
IGT								
2-h PG ≥140 mg/dl and <200 mg/dl	375 (28.1)	168.4 ± 62.6	119	64.7	65.5	27.2	0.715	65.4
IFG (WHO)								
FPG ≥110 mg/dl and <126 mg/dl	385 (28.9)	165.0 ± 63.1	118	62.8	62.9	25.4	0.683	62.9
IFG (ADA)								
FPG ≥100 mg/dl and <126 mg/dl	633 (47.5)	146.9 ± 57.1	113	58.3	58.6	46.9	0.619	58.5
Abnormal glucose tolerance								
IGT and diabetes	220 (16.5)	191.8 ± 67.1	141	82.3	82.4	48.0	0.888	82.4
Abnormal glucose regulation								
IFG (WHO) or IGT or diabetes	497 (37.3)	157.5 ± 59.3	121	70.2	69.9	58.1	0.777	70.0
IFG (ADA) or IGT or diabetes	698 (52.4)	145.4 ± 55.5	116	66.5	65.5	68.0	0.714	66.0

Data are means ± SD unless otherwise indicated. AUC, area under the curve; PG, plasma glucose; PPV, positive predictive value.

points, and areas under the curve were plotted. By interpolation from the area under the curve, the point closest to the upper-left corner, which maximized sensitivity and specificity, was selected; this identified the highest number of subjects with or without a diabetes condition (11). In this manner, RCBG cut points were determined for diabetes, IGT, and IFG using ADA (8) and WHO (9) criteria (supplemental Figure 1*A*, available in an online appendix at http://care.diabetesjournals.org/cgi/content/full/dc08-0403/DC1).

RESULTS — For the study group, mean ± SD age was 45.5 ± 10.7 years, BMI was 24.8 ± 4.0 kg/m^2, and 45.2% were men. Additionally, 27.2% (n = 363) had RCBG <100 mg/dl (5.6 mmol/l), 65.9% (n = 878) had RCBG in the range of 100–200 mg/dl (5.6–11.1 mmol/l), and 6.9% (n = 92) had RCBG >200 mg/dl (11.1 mmol/l).

Using the 2-h plasma glucose ≥200 mg/dl (11.1 mmol/l) criterion, the RCBG cut point of 140 mg/dl (7.7 mmol/l) gave the highest sensitivity and specificity (Table 1). Using the 2-h plasma glucose ≥200 mg/dl (11.1 mmol/l) and FPG ≥126 mg/dl (7.0 mmol/l) criteria, either 2-h plasma glucose ≥200 mg/dl (11.1 mmol/l) or FPG ≥126 mg/dl (7.0 mmol/l) criterion, or for FPG ≥126 mg/dl (7.0 mmol/l) criterion, the RCBG cut point was 143 mg/dl (7.9 mmol/l).

For IGT, the RCBG cut point was 119 mg/dl (6.6 mmol/l). Using the IFG (WHO) criterion of FPG ≥110 (6.1 mmol/l) and <126 mg/dl (7.0 mmol/l), the RCBG cut point was 118 mg/dl (6.6 mmol/l), while for the IFG (ADA) criterion of FPG ≥100 mg/dl (5.6 mmol/l) and <126 mg/dl (7.0 mmol/l), the RCBG cut point was 113 mg/dl (6.3 mmol/l).

CONCLUSIONS — The most commonly used tests for screening for type 2 diabetes are FPG and 2-h plasma glucose (9,10). Measurement of RCBG has an advantage in that it can be undertaken at any time of the day, does not require a venipuncture, and can even be performed by laypeople. In studies from North America, RCBG cut points ranging from 99 to 140 mg/dl have been reported to identify diabetes (5,12–14).

Our study presents the first such data from India and shows that, in Asian Indians, RCBG cut points of 140 and 143 mg/dl (7.8 and 7.9 mmol/l) maximized the sensitivity and specificity for diabetes. Moreover, this study provides the first data, to our knowledge, on RCPG cut points for IGT (119 mg/dl [6.6 mmol/l]), two definitions of IFG (WHO 118 mg/dl and ADA 113 mg/dl), and abnormal glucose tolerance (141 mg/dl) and regulation (121 mg/dl).

The strengths of this study are that it is based on a large number of subjects, was performed in a "real life" community-based setting, and is the first, to our knowledge, to report on cut points for IGT and IFG according to WHO and ADA criteria.

Based on the findings of our study, we propose that in opportunistic screening studies in Asian Indians, all those with RCBG values >110 mg/dl (6.1 mmol/l) should receive more definitive tests for diabetes and pre-diabetes. This could not only help limit the number of individuals who must arrive for screening in a fasting state but also reduce the costs of screening, as only 60% of those screened would have RCBG >110 mg/dl.

Acknowledgments— We thank the Chennai Willingdon Corporate Foundation for their financial support.

No potential conflicts of interest relevant to this article were reported.

References

1. Harris MI: Undiagnosed NIDDM: clinical and public health issues. *Diabetes Care* 16: 642–652, 1993
2. Mohan V, Deepa M, Deepa R, Shanthirani CS, Farooq S, Ganesan A, Datta M: Secular trends in the prevalence of diabetes and impaired glucose tolerance in urban south India–the Chennai Urban Rural Epidemiology Study (CURES-17). *Diabetologia* 49:1175–1178, 2006
3. Harris MI, Klein R, Wellborn TA, Knuiman MW: Onset of NIDDM occurs at least 4–7 years before clinical diagnosis. *Diabetes Care* 15:815–819, 1992
4. American Diabetes Association: Screening for type 2 diabetes (Position Statement). *Diabetes Care* 27:S11–S14, 2004

5. Engelgau MM, Thompson TJ, Smith PJ, Herman WH, Aubert RE, Gunter EW, Wetterhall SF, Sous ES, Ali MA: Screening for diabetes mellitus in adults: the utility of random capillary blood glucose measurements. *Diabetes Care* 18:463–466, 1995
6. Andersson DK, Lundblad E, Svardsudd K: A model for early diagnosis of type 2 diabetes mellitus in primary health care. *Diabet Med* 10:167–73, 1993
7. Sicree R, Shaw J, Zimmet P: Diabetes and impaired glucose tolerance in India. In *Diabetes Atlas*. Gan D, Ed. Belgium, International Diabetes Federation, 2006, p. 15–103
8. The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus: Follow-up report on the diagnosis of diabetes mellitus (Committee Report). *Diabetes Care* 26:3160–3167, 2003
9. World Health Organization: *Definition and Diagnosis of Diabetes Mellitus and Intermediate Hyperglycemia: Report of a WHO/IDF Consultation*. Geneva, World Health Org., 2006. Available from http://www.idf.org/webdata/docs/WHO_IDF_definition_diagnosis_of_diabetes.pdf.
10. Somannavar S, Lanthorn H, Pradeepa R, Narayanan V, Rema M, Mohan V: Prevention Awareness Counselling and Evaluation (PACE) Diabetes Project: a mega multi-pronged program for diabetes awareness and prevention in South India (PACE-5). *J Assoc Physicians India* 56:429–435, 2008
11. Hanley JA, McNeil BJ: The meaning and use of the area under a receiver operating characteristic (ROC) curve. *Radiology* 143:29–36, 1982
12. Leiter LA, Barr A, Bélanger A, Lubin S, Ross SA, Tildesley HD, Fontaine N: Diabetes Screening in Canada (DIASCAN) Study: prevalence of undiagnosed diabetes and glucose intolerance in family physician offices. *Diabetes Care* 24:1038–1043, 2001
13. Rolka DB, Narayan KMV, Thompson TJ, Goldman D, Lindenmayer J, Alich K, Bacall D, Benjamin EM, Lamb B, Stuart DO, Engelgau MM: Performance of recommended screening tests for undiagnosed diabetes and dysglycemia. *Diabetes Care* 24:1899–1903, 2001
14. Zhang P, Engelgau MM, Valdez R, Cadwell B, Benjamin SM, Narayan KMV: Efficient cutoff points for three screening tests for detecting undiagnosed diabetes and pre-diabetes: an economic analysis. *Diabetes Care* 28:1321–1325, 2005